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EXAMINER

RAMANA, ANURADHA

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 17

Application Number: 09/815,567
Filing Date: March 23, 2001
Appellant(s): PARKER, FRED T.

Lawrence A. Steward
For Appellant

MAILED
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GROUP 3700

EXAMINER'S ANSWER

This is in response to the appeal brief filed on July 21, 2003.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

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Appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is deficient because of a minor typographical error on line 12 (page 3): "inner coil" should be "inner tube."

(6) *Issues*

Appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-21 stand or fall together.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

5,792,124	Horrigan et al.	08-1998
6,159,187	Park et al.	12-2000
5,380,304	Parker	01-1995
6,210,396	MacDonald et al.	04-2001
5,599,325	Ju et al.	02-1997

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. *Claims 1-2, 4-5, 10-13, and 15-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. (US 5,792,124) in view of Park et al. (US 6,159,187).*

Regarding claim 1, Horrigan et al. disclose a catheter or sheath having a unitary lubricous liner or inner tube 40; a reinforcement means or wire braid 35 terminating proximal to the distal end of inner tube 40; a first outer tube 15; a second outer tube 20 wherein the second outer tube 20 is made of softer material than the first outer tube 15 (Figure 3; col. 2, lines 60-67; col. 3, lines 1-20; and col. 8, lines 28-34); and a distal tip 45. Further, Horrigan et al. teach the use of wire braid 35 to offer better kink resistance (col. 5, lines 1-3).

Horrigan et al. do not disclose the use of a flat wire coil as a reinforcement means.

Park et al. teach a catheter section or sheath with a braided wire coil (Figure 7) for better kink resistance (col. 2, lines 40-43; col. 13, lines 64-67; and col. 14, lines 1-26). Further, Park et al. teach the importance of designing the sheath to enable its manipulation through increasingly small blood vessels (col. 1, lines 30-52).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the wire braid 35 of Horrigan et al. with a braided wire coil as disclosed by Park et al. to have facilitated the manufacture of the catheter or sheath with a diameter suitable for application in an environment of increasingly small diameters.

Regarding claim 2, Horrigan et al. disclose that the materials of the outer jacket of the sheath including the inner tube 40, wire braid 35, first outer tube 15 and second outer tube 20 are bonded (col. 5, lines 47-56).

Regarding claim 4, Horrigan et al. further disclose that the inner tube 40; the wire braid 35; the first outer tube 15 and the second outer tube 20 are fused or bonded by heating (col. 5, lines 47-56).

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Regarding claim 5, although the Horrigan et al. device does not include a radiopaque marker band, attention is again directed to Park et al., which disclose a radiopaque marker band 120 in the distal region of a catheter or sheath 114 to allow viewing of the position of the distal most portion of the sheath 114 (col. 9, lines 25-33). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radiopaque marker band 120 as taught by Park et al. in the second outer tube 20 of the Horrigan et al. device for viewing the position of the distal tip 45 of the Horrigan et al. device.

Regarding claims 10-13, Horrigan et al. further disclose a second outer tube 20 made of a material having a hardness range of Shore durometer 25D to 40D and a first outer tube 40 having a hardness range of Shore durometer 50D to 60D.

Regarding claim 15, Park et al. teach a wire coil 232 made of one or more ribbons or "flat wire" (Figure 7 and col. 14, lines 15-17).

Regarding claim 16, Park et al. teach a sheath 110 having an arcuate distal tip region 112 (Figure 2 and col. 9, lines 21-24).

Regarding claim 17, Park et al. teach a sheath 110 having an arcuate distal tip region 112 with a typical length of 2.5 cm to 30 cm (col. 9, line 40).

Regarding claim 18, Park et al. teach a sheath 110 having an arcuate distal tip region 112 that is a quadrant of a circle (Figure 2 and col. 9, lines 21-24).

Regarding claim 19, Horrigan et al. disclose that the wire braid 35 should not extend more than 1/3 the length of the second outer tube 20 to provide optimum flexibility of tip 45 (col. 5, lines 1-9) or approximately 3 mm (col. 5, lines 16-20).

Regarding claim 20, Horrigan et al. disclose a sheath having a unitary lubricous liner or inner tube 40.

2. Claim 3 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. in view of Park et al. as applied to claim 1 above, further in view of Parker (US 5,380,304).

Although Horrigan et al. do not disclose a roughened surface, attention is directed to the Parker reference, which teaches an inner tube 22 having an outer rough surface; a wire coil 23; and an outer tube 12 wherein the outer tube 12 is mechanically connected or bonded to the inner

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tube 22 and the wire coil by the well-known heat shrinking and formation process (col. 3, lines 67-68 and col. 4, lines 1-3).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the sheath of Horrigan et al. by roughening the outer surface of inner tube 22, as taught by Parker, in order to improve bonding between the outer tube 12, the wire coil 23 and the inner tube 22.

3. Claims 6-9 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. in view of Park et al., further in view of Ju et al (US 5,599,325).

Regarding claim 6, Horrigan et al. do not disclose a sheath wherein the second outer tube 20 of the sheath contains radiopaque filler.

Ju et al. teach a sheath 10 wherein the distal end portion of the stem member 34 is a soft tip member 40 made from a polymer and radiopaque filler blend (col. 6, lines 6-14).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a second outer tube 20 in the sheath of Horrigan et al. wherein the second outer tube 20 is made from a blend of polymer and radiopaque filler as taught by Ju et al. in order to allow viewing of the position of the sheath in the human body.

Regarding claim 7, Ju et al. further disclose a sheath 10 with an outer layer containing 0 to 42 percent by weight of radiopaque filler, which is the claimed range of about 20% to 85%.

Regarding claim 8, Ju et al. disclose a sheath 10 with a second outer tube containing 0 to 42 percent by weight of radiopaque filler, which is "about 80%" as claimed.

Regarding claim 9, Ju et al. further disclose a sheath 10 with a first outer tube containing 0 percent by weight of radiopaque filler, which is substantially free of radiopaque filler.

Regarding claim 21, see the discussion for claims 1, 6, 10, 15, 17 and 19.

4. Claim 14 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. in view of Park et al. as applied to claim 1 above, further in view of MacDonald et al (US 6,210,396).

Horrigan et al. do not disclose a sheath wherein the first outer tube 15 and the second outer tube 20 are of different colors or shades.

MacDonald et al. teach a catheter body or sheath 15 having a sleeve 120, a distal catheter shaft 35, a radiopaque band 140 and a distal soft tip 40 wherein the color of the sleeve 120 is different from the color of the distal catheter shaft 35, the color of the radiopaque band 140 and the color of the distal soft tip 40 for identification purposes (col. 10, lines 57-62).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided different colors to the first outer tube 15 and the second outer tube 20 in the sheath of Horrigan et al. as taught by MacDonald in order to enable a user to identify the first and the second tubes.

(11) *Response to Arguments*

Appellant contends on pages 4-7 of the brief that the combination of Horrigan et al. and Park et al. do not teach a thin-walled device. Appellant's argument is improper for the following reasons.

Contrary to Appellant's assertion that a wire braid is not suitable as reinforcement for thin-walled construction of an intravascular device such as an introducer sheath, Horrigan et al. disclose the use of wire braid 35 as reinforcement for a thin-wall guiding catheter or "intravascular device" having a wall thickness less than 0.3 mm (col. 2, lines 45-49 and col. 4, lines 21-22). Appellant's argument on page 5 of the brief, that a braided reinforcement has an enlarged diameter when compared to a wire coil is flawed because it assumes a woven braid of a material having a round cross section such as a wire or thread and does not consider a braid made of a material such as a flat ribbon. Appellant's attention is directed to Park et al. who teach that a braid made of a flat ribbon has a lower profile than a braid made of a material having a round cross section (Figures 3 and 4 and col. 13, lines 53-63).

Regarding Appellant's assertion on page 5 of the brief, that a wire coil has greater kink resistance than a wire braid, Appellant's attention is directed to Park et al. who teach the equivalence of a braid or a coil for reinforcement of an intravascular device for use in an environment of increasingly small diameters for resistance to kinking (col. 1, lines 9-11 and lines 29-52 and col. 8, lines 29-36). Specifically, Park et al. teach a braid with one or more coils wherein the coil is a wire having a round cross section or is "flat wire" or a ribbon for the

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purpose of reinforcing intravascular devices with small overall diameters for exceptional kink resistance (Figures 3-9, col. 13, lines 65-67 and col. 14, lines 1-26). Thus, the combination of Horrigan et al. and Park et al. discloses the Appellant's invention.

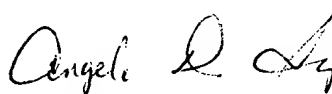
For the above reasons, it is believed that the rejections should be sustained.

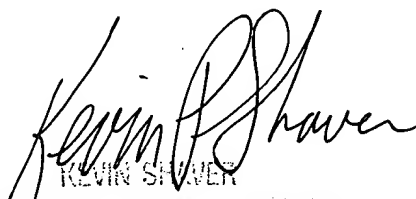
Respectfully submitted,

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